Inspection report on compliance with HTA licensing standards
Inspection date: **26 (remote assessment) and 27 (site visit) November 2025**

Northwick Park Institute for Medical Research (NPIMR) (The Griffin Institute)
HTA licensing number 12700

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
NPIMR (The Griffin Institute)	Not licensed	Licensed	Licensed	Not licensed

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that The Griffin Institute ('the establishment') had met most of the HTA's standards one minor shortfall was identified against Premises, facilities and equipment standards; this was in relation to storage arrangements for cadaveric material.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfall identified during the inspection.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
b) Storage arrangements ensure the dignity of the deceased.	During the inspection, establishment staff experienced difficulty removing two frozen bodies from storage. Although this issue was resolved following the inspection, similar problems were reported to have happened several times in the past, posing risks of physical damage and compromising the dignity of deceased donors. The establishment did not have a documented procedure to support the safe removal and handling of frozen bodies or parts from storage. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ2(a)	The establishment has an approach to audits which involves internal and external audits being undertaken regularly. An internal audit is undertaken every two months. The DI should consider including a physical check of bodies during the audits to identify any issues linked to storage, in light of the shortfall identified during the inspection. This may help to identify any storage problems more proactively.
2.	PFE1(b)	The keys to access the mortuary freezer room are kept in a lock-box outside of the main mortuary room. There are plans to change the security access system to the mortuary. In the interim, the DI should consider changing the lock-box code regularly as this may help to ensure that security measures are further strengthened.
3.	PFE2(c)	The establishment carries out a regular alarm challenge for the freezers and fridges. To strengthen the approach further the DI should consider incorporating a review of whether staff follow the procedure in response to an alarm notification. This will help to ensure that the whole process from alarm notification to response is reviewed.

4.	PFE2(d)	The establishment has appropriate on-site contingency arrangements. Although the DI does have arrangements for off-site contingency with a HTA-licensed premises, the DI should consider documenting these arrangements in their existing procedure in the event that off-site contingency is required unexpectedly.

Background

The establishment has been licensed by the HTA since 2020. This was the first inspection of the establishment.

The establishment sources cadaveric material from within the UK and outside of the UK. The material is stored and used in surgical training for clinicians or trainee surgeons. All material has consent for use in education and training and research. Once the material has been used it will be cremated or returned to its supplier for cremation.

The establishment plans to carry out some storage for related research using the bodies and body parts in the future. They also plan to store prosections for anatomical teaching.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

Out of the total 47 standards, 39 were assessed. C1(a),(b),(d), (e), (f) and C2(a), (b) and (c) were not applicable as the establishment is not involved in seeking consent.

Review of governance documentation
During the inspection policies and procedural documents relating to licensed activities, cleaning records for the storage areas, records of servicing, internal audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents and staff training records were reviewed.

Visual inspection
The visual inspection comprised of review of the fridges and freezers where cadaveric material is stored and thawed in preparation for surgical training.

Audit of records

An audit trail of records and cadaveric material in storage was undertaken.

A ‘forward’ audit of two bodies that had been used in surgical courses was undertaken. The bodies were identified from their storage location in the freezer and associated records were reviewed, including donor consent, screening, agreements and traceability records linked to receipt through to their use in courses. All records clearly showed when the donors were removed from the freezer, thawed, used and then placed back into their respective freezer locations. There were no discrepancies identified.

A ‘forward’ audit of two body parts was also undertaken. The parts were identified from the storage locations in the freezer and associated records were reviewed, including donor consent, screening, agreements and traceability records linked to receipt through to their use in courses. All records clearly showed when parts were removed from the freezer, thawed, used and then placed back into their respective freezer locations. There were no discrepancies identified.

Records associated with disposal or return of cadaveric material were also reviewed. No discrepancies were identified.

Meetings with establishment staff

The inspection involved meeting with the DI, Person Designated (PD) and Quality Lead.

Report sent to DI for factual accuracy: 18 December 2025

Report returned from DI: 8 January 2026 (no comments)

Final report issued: 9 January 2026

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk-based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.